

## REMARKS

### **A. Status of Claims**

Applicant's undersigned representative appreciates the Examiner's thorough review and correction of claim status set forth at page 2 of the subject Action, and apologizes for the past confusion. The foregoing amendments, as set forth above and explained below, are believed to address the concerns and place the claim status in proper form.

Claims 97-99, 116-122, 133-137, 141-143 and 150 are currently pending. Claim 97 has been amended to place it into independent form. Claims 16-23, 26-92 and 100-105 have been cancelled without prejudice as drawn to non-elected inventions. Independent claim 93 has been cancelled and dependent claim 97 amended to place it into independent form. Claims 99, 116, 133 and 141-142 have been amended to change their dependency to depend from claim 97 or claim 150.

Claims 94-96, 106-115, 123-132, 138-140 and 144-149 currently stand withdrawn on the basis of the Action's position that there was previously no allowable generic claim. For reasons set forth below, it is submitted that a generic linking claim, claim 97, is now allowable and, thus, reinstatement of these withdrawn claims is respectfully requested. Upon reinstatement, these claims will require some amendment to change dependencies from claim 93 to 97 (claims 94-96, 106-107, 109, 129-133, 138-139). Further, upon reinstatement Applicant will desire to amend claims 107 and 109 to clarify that "more than" 95% and 97%, respectively, of the solvent or acid is removed.

**B. Section 112, Second Paragraph Rejections**

The Action first rejects claims 93, 97-98, 116-122, 133-137 and 141-143 on the basis of 35 U.S.C. §112, second paragraph, taking the position that the meaning of “virtually eliminated” was not evident to the Examiner. To address this concern, the main claim, claim 97, has been amended to recite a numerical designation (“more than 50%”), support for which was acknowledged by the subject Action.

**C. Personal Interview/Section 112, First Paragraph Rejections**

The Examiner kindly granted Applicant’s request for a personal interview, which was held on August 7, 2003. The substance of the interview focused on the §112, first paragraph, rejections which concerned whether the specification adequately described a solvent vehicle apart from use in connection with pimaricin, which could be used for solubilizing drugs other than pimaricin. Applicant’s representative directed the Examiner’s attention first to the specification at page 14, lines 24-25, which recited that the solvent vehicles themselves were considered by the inventor to be separately “novel.” Next, Applicant’s representative directed the Examiner’s attention to Table 2 on page 20, and the accompanying text, which provided an analysis of various solvent vehicles within the scope of the current claims separate and apart from the same solvent vehicles used to solubilize pimaricin *per se*. The Examiner agreed that this text overcame his §112, first paragraph concerns.

**D. Prior Art Issues**

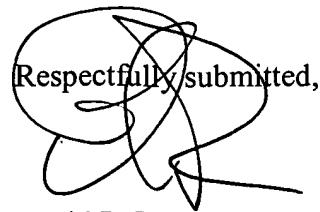
The only rejection remaining of record is a rejection of claims 93, 99, 116, 117, 133 and 141 over Szoka Jr. ‘910 and Szoka Jr. ‘914. In that claim 97 was not subject to rejection, claim 97, and claims depending therefrom, are free of the art.

In any event, the Szoka Jr. patents are not believed to be particularly relevant to the subject invention, for the reason that these patents do not appear to concern first solubilization of a drug in an appropriate aprotic solvent, followed by introduction of an aqueous phase, substantial removal of the organic solvent/aqueous phase, following by reconstitution in a *second* aqueous solution. Rather, these patents are concerned with the preparation of liposomal drug formulations.

At the interview referred to above, Applicant's representative indicated to the Examiner that a search of the art had recently been performed by the Applicant's representative. The results of this search has been made of record concurrent with the present response. Applicant makes no representation that this search is in any way exhaustive or even necessarily representative. Nevertheless, it is believed that the results of this search provide further confirmation of the novelty and non-obviousness of the present solvent vehicles. Of the enclosed art, the most relevant appears to be Janoff *et al.* '713 patent (see particularly, 2<sup>nd</sup> para. of Summary of the Invention section). However, Janoff *et al.* is believed to be irrelevant for much the same reasons as the Szoka Jr. patents, in that it relates to liposomal or liposomal-like suspensions and do not appear to involve solubilization of a drug in an appropriate aprotic solvent, followed by introduction of an aqueous phase, substantial removal of the organic solvent/aqueous phase, following by reconstitution in a *second* aqueous solution.

#### **E. Conclusion**

Applicants respectfully request favorable consideration of this case in view of the above. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicant's representative at (512)-536-3055.

Respectfully submitted,  


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